

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CUBIST PHARMACEUTICALS, INC., )

Plaintiff, )

v. )

HOSPIRA, INC., )

Defendant. )

C.A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Cubist Pharmaceuticals, Inc., by its attorneys, alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Hospira, Inc. of Abbreviated New Drug Application (“ANDA”) No. 202857 with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of CUBICIN<sup>®</sup> prior to the expiration of U.S. Patent No. 8,129,342.

**PARTIES**

2. Plaintiff Cubist Pharmaceuticals, Inc. (“Cubist”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

3. Upon information and belief, Defendant Hospira, Inc. (“Hospira”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois.

4. Hospira manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

### **JURISDICTION AND VENUE**

5. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

7. Hospira is subject to personal jurisdiction in Delaware because, among other things, it has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law. Hospira is also subject to personal jurisdiction in Delaware because, among other things, Hospira manufactures, markets, and sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

### **BACKGROUND**

8. CUBICIN<sup>®</sup> (daptomycin for injection) is an intravenous bactericidal antibiotic approved by the FDA for the treatment of complicated skin and skin structure infections caused by certain Gram-positive microorganisms, such as *Staphylococcus aureus*, including methicillin-resistant strains, also known as MRSA. CUBICIN<sup>®</sup> is also approved for the treatment of *S. aureus* bloodstream infections (bacteremia), including right sided infective endocarditis caused by MRSA.

9. Cubist sells CUBICIN<sup>®</sup> in the United States pursuant to a New Drug Application that has been approved by the FDA.

10. United States Patent No. 8,129,342 (“the ’342 patent”), entitled “High Purity Lipopeptides” (Exhibit A hereto), was duly and legally issued on March 6, 2012. The ’342 patent, which is owned by Cubist, will expire on November 28, 2020.

11. CUBICIN<sup>®</sup> is covered by one or more claims of the '342 patent, which has been listed in connection with CUBICIN<sup>®</sup> in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

12. By letter dated May 31, 2012 (the "Notice Letter"), Hospira notified Cubist that it had submitted an amendment to the FDA for its previously submitted ANDA No. 202587 for Daptomycin for Injection, 500 mg/vial, a generic version of CUBICIN<sup>®</sup> ("Hospira's ANDA Product").

13. In the Notice Letter, Hospira stated that its ANDA had been amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '342 patent and alleged that the '342 patent was invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Hospira's ANDA Product.

14. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

### **CLAIM FOR RELIEF**

#### **INFRINGEMENT OF U.S. PATENT NO. 8,129,342**

15. Plaintiff incorporates each of the proceeding paragraphs 1 - 14 as if fully set forth herein.

16. Hospira's ANDA Product is covered by one or more claims of the '342 patent.

17. Hospira's submission of ANDA No. 202857 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's ANDA Product before the expiration of the '342 patent is an act of infringement of the '342 patent.

18. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira's ANDA Product would infringe one or more claims of the '342 patent.

19. Unless Hospira is enjoined from infringing the '342 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays that this Court grant the following relief:

(a) A judgment that Hospira's submission of ANDA No. 202857 and its amendment thereto was an act of infringement of the '342 patent, and that Hospira's manufacture, use, offer to sell, sale, or importation of Hospira's ANDA Product prior to the expiration of the '342 patent will infringe the '342 patent;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Hospira's ANDA No. 202857, or any product or compound that infringes the '342 patent, shall not be earlier than the expiration of the '342 patent;

(c) An Order permanently enjoining Hospira, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Hospira's ANDA Product, or any product or compound that infringes the '342 patent until after the expiration of the '342 patent;

(d) A declaration that this is an exceptional case and an award of attorneys' fees to plaintiff pursuant to 35 U.S.C. § 285;

(e) Plaintiffs reasonable costs of suit incurred; and

(f) Such further and other relief as this Court deems proper and just.

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